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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,048	12/27/2001	Ernst Heinz	0093/000032	5170

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EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/019,048	HEINZ ET AL.	
	Examiner	Art Unit	
	CATHERINE HIBBERT	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8-10 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8-10 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on 29 April 2010 has been entered.

Claims 2-5, 7, 11-12 and 14-21 are cancelled. Claims 1, 6, 8-10 and 13 are pending and under examination in this action. This action is NON-FINAL.

Response to Amendment

All objections/rejections not repeated herein are withdrawn.

37 CFR 1.131 Declaration

The Declaration of Dr. Ernst Heinz filed under 37 CFR 1.131 on 29 April 2010 has been considered and is **effective** to overcome the Doctoral Theses of Girke reference.

The Declaration of Dr. Ernst Heinz filed under 37 CFR 1.131 on 29 April 2010 has been considered but is **ineffective** to overcome the Girke et al. (Plant J., July, 1998, Vol. 15(1), pp. 39-48) reference.

Dr. Heinz provides in the Declaration that Girke, Scheffler, Da COSTA e SILVA and Heinz are the sole co-inventors of the invention described and claimed in US Application 10/019,048. In addition, Heinz declares that Heinz and Girke are co-authors of the Girke et al (Plant J., July, 1998, Vol. 15(1), pp. 39-48) reference. In addition, Heinz states that the Reference 1 which is mentioned in the "SCORE Search Result Details..." enclosed with the Office action on 3 February 2010 is an Abstract of the Girke et al (Plant J., July, 1998, Vol. 15(1), pp. 39-48) reference. In addition, Heinz states that each disclosure of the embodiments which relate to the subject matter disclosed and claimed in 10/019,048 which was made in the Girke et al (Plant J., July, 1998, Vol. 15(1),

pp. 39-48) reference, was made by Heinz and/or by Girke, and that each such disclosure was made on their own behalf and on behalf of their co-inventors.

The Declaration has been fully considered but is insufficient to overcome the Girke et al reference (Plant J, July, 1998, Vol. 15, No.1, pp 39-48) because the inventive entity of the reference consists of all of the co-authors: Girke, Schmidt, Zahringer, Reski and Heinz and the Heinz Declaration does not address the co-authors Schmidt, Zahringer, Reski anywhere in the Declaration. Please see MPEP 2132 which states that applicant "can rebut *prima facie* case by showing reference's disclosure was derived from applicant's own work" and further states:

> Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (discussed below). Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. Ex parte Hirschler, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). However, if there is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish that applicant is the sole inventor and the rejection will stand. *Ex parte Kroger*, 219 USPQ 370 (Bd. Pat. App. & Int. 1982) (discussed below). It is also possible to overcome the rejection by adding the coauthors as inventors to the application if the requirements of 35 U.S.C. 116, third paragraph are met. *In re Searles*, 422 F.2d 431, 164 USPQ 623 (CCPA 1970). In *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), Katz stated in a declaration that the coauthors of the publication, Chiorazzi and Eshhar, "were students working under the direction and supervision of the inventor, Dr. David H. Katz." The court held that this declaration, in combination with the fact that the publication was a research paper, was enough to establish Katz as the sole inventor and that the work described in the publication was his own. In research papers, students involved only with assay and testing are normally listed as coauthors but are not considered co-inventors.

Priority

Priority for the claimed invention is granted back to the filing date of the 09/347,531 application, filed 7/6/1999.

Response to Arguments-rejections under 35 U.S.C. §102(a) and §103(a)

The rejection of Claims 1 and 8-9 under 35 U.S.C. 102(a) as being anticipated by Girke et al. (Plant J., July, 1998) and the rejection of Claims 6 and 10 under 35 U.S.C. 103(a) as being unpatentable over Girke et al in further view of Napier et al are maintained and restated below.

Applicants' arguments have been fully considered but are not found persuasive.

Applicants response is to traverse the rejections. Applicants REMARKS filed 4/29/2010 have been fully considered. Applicants argue that as "evidenced by the enclosed Declaration of Prof. Heinz, each disclosure of the embodiments which relate to the subject matter disclosed and claimed in U.S. Application Serial No. 10/019,048 which was made in

> -the publication "Identification of a novel A6-acyl group desaturase by targeted gene disruption in Physcomitrella patens", which was published on July 27, 1998, in The Plant Journal 15(1), 39-48 (1998);

was made by Prof. Heinz and/or by his co-inventor Dr. Girke, and that each such disclosure was made on their own behalf and on behalf of their co-inventors (citation to Prof. Heinz's Declaration No. 9)". Thus, Applicants argue "since the application is entitled to the filing date of application Serial. No. 09/347,531, filed on July 06, 1999", that:

1) the teaching of Girke et al. (Plant J. 15(1), 39-48 (July 27, 1998)), published on July 27, 1998, upon which the rejections in (a) and (b) rely does not fall within the realm of prior art under Section 102(a) because the invention was NOT "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by" applicants;

Applicants' arguments have been fully considered but are not found persuasive because the Declaration of Dr. Ernst Heinz filed under 37 CFR 1.131 on 29 April 2010 upon which Applicant relies is ineffective to overcome the Girke et al. (Plant J., July, 1998, Vol. 15(1), pp. 39-48) reference for reasons provided above.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 8-9 STAND rejected **and claim 13 is newly rejected** under 35 U.S.C. 102(a) as being anticipated by Girke, Schmidt, Zahringer, Reski and Heinz (Plant J., July, 1998, Vol. 15(1), pp. 39-48, of record in the IDS; and referenced by Score Report result for SEQ ID NO:1 and NO:2) for reasons of record and presented herein.

Claims 1 and 8 are drawn to a process of preparing an unsaturated fatty acid, which comprises introducing, into an organism being a yeast or plant, at least one isolated nucleic acid sequence encoding a polypeptide having Δ6-desaturase activity, selected from the group consisting of:

(a) A nucleic acid sequence having the sequence shown in SEQ ID NO:1,

(b) nucleic acid sequences which, as a result of the degeneracy of the genetic code, are derived from the sequence shown in SEQ ID NO:1, and

(c) a derivative of the nucleic acid sequence shown in SEQ ID NO:1 which encodes the polypeptide with the amino acid sequence shown in SEQ ID NO:2 or a polypeptide having at

least 95% homology at the amino acid level said polypeptide still having Δ 6-desaturase catalytic activity,

and culturing the organism to express the polypeptide and isolating the unsaturated fatty acid from the organism.

Claim 9 reads on a transgenic yeast comprising an isolated nucleic acid sequence comprising the sequence shown in SEQ ID NO:1. Claim 13 is drawn to an isolated nucleic acid comprising SEQ ID NO:1.

Girke et al. teach identification and expression of a A6-desaturase (D6D) from P. patens (PPDES6) (e.g., Abstract). The reference teaches that the cDNA for PPDES6 is 2012 bp, i.e., SEQ ID NO: 1. (e.g., p. 40, col. 1, last full paragraph) and see Score Report "Result 2" which shows a nucleic acid sequence with 100% identity to the instant SEQ ID NO:1 which is to the 2012 bp mRNA sequence encoding the delta6-acyl-lipid desaturase of *P. patens* submitted as pertaining to the Girke et al journal article published July 1998 (Plant J. 15, pages 39-48).

In addition, the reference teaches expression of PPDES6 in the yeast strain *S. cerevisiae*. (e.g., p. 45, col. 2, ¶ 3). Furthermore, expression of PPDES6 in the cells (i.e., cultured cells) produces concentrations of unsaturated fatty acids that are at least 1 or 5%, whereby to measure the concentration of said fatty acids, each would inherently have to be isolated from the yeast cells. (e.g., p. 45, col. 1, Table 1).

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 10 STAND rejected under 35 U.S.C. 103(a) as being unpatentable over Girke et al., as applied to Claims 1 and 8-9 and 13 above, in further view of Napier et al (of record).

Girke et al. teach expression of PPDES6 (instant SEQ ID NO:1) in yeast and yeast cells as described above.

The Girke et al. reference does not explicitly teach expression of PPDES6 in plants or an oil crop. However, the reference implies that the desaturase, such as PPDES6 isolated from moss, is a good source for producing a wider variety of polyunsaturated fatty acids (UFAs). (e.g., p. 39, under "Introduction"). In any event, utilization of D6Ds to modify the lipid composition in oilseed crop was a primary focus in the art at the time of invention. For example, Napier et al.

discuss utilizing desaturases from different sources for producing a wider variety and beneficial UFAs. (e.g., Abstract; p. 123). More particularly, the reference explicitly notes that the D6D isolated from *P. patens* is another D6D, in the same vein as producing fatty acids in transgenic oilseed crop. (e.g., p. 125, ¶ 1). The primary thrust of Napier et al is that expression of desaturases in transgenic plants will lead to production of 'designer oil[s]' in said plants so as to meet the demands of the pharmaceutical and chemical industry. (e.g., p. 126, last paragraph).

Therefore, it would have been obvious to utilize the PPDES6 desaturase as taught by Girke in plants or oilseed crop. One would have been motivated to make such transgenic plants and to produce UFAs therein, so as to utilize PPDES6, with the benefit of extending the range of beneficial designer oils or UFAs produced. Furthermore, given the level of skill at the time of invention, there would have been a reasonable expectation of success in producing UFAs in a plant, transformed with PPDES6.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT, whose telephone number is (571)270-3053. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Catherine Hibbert
Examiner AU1636